DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1126B

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-52795

January 23, 1997

Carl G. Van Vliet
C.G. Van Vliet Dairy
29984 East Highway 120
Escalon, California 95320

WARNING LETTER

Dear Mr. Van Vliet:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 3, 1997, by Food and Drug Administration (FDA) Investigator John A. Gonzalez, have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On November 21, 1996, you consigned a bull calf (identified by USDA laboratory report number 256417) for sale for slaughter as human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of oxytetracycline at a level of 0.73 parts per million (ppm) in the kidney tissue. Prior to December 23, 1996, the tolerance level for oxytetracycline had been established at 0.1 ppm in the uncooked edible tissues of beef calves. Presently, the tolerance levels for oxytetracycline in the uncooked edible tissues of beef calves has been established at 2 ppm in muscle tissues, 6 ppm in liver tissues, and 12 ppm in fat and kidney tissues.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions... whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The AgriLabs brand of tetracycline hydrochloride soluble powder that your establishment uses on dairy and beef calves is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(w), and it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Labeling for AgriLabs tetracycline hydrochloride recommends that it be used as a drench or by dose syringe and warns against releasing calves for slaughter for food within five days after the last treatment. Your practice of filling gelatin capsules with tetracycline hydrochloride to create an oral infusion to medicate your dairy and beef calves is an unapproved use for which safety and efficacy has not been proven. Creating the infusion constitutes manufacturing a new animal drug which requires the submission of a New Animal Drug Application for FDA approval.

You are using the drug penicillin G procaine in a manner not in conformance with its approved labeling directions. The labeling for penicillin G procaine specifies it is to be administered at a dosage of 1 milliliter (mL) per 100 pounds of body weight. Your practice of administering a daily total dosage of 40 mLs into dairy cows weighing an average of 1400 pounds results in a dosage in excess of that allowed by the drug's labeling directions.

Failure to adhere to labeling directions, including recommended withdrawal times, and to maintain a written record of all drugs administered to your cattle, are likely the causes of the illegal residues found in the calf you sold for slaughter. Failure to comply with the label instructions on a drug presents the possibility that illegal residues will occur and makes the drug unsafe.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt into interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the current inspection and in this letter, and should include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to John M. Reves, Compliance Officer.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]